

EXHIBIT 1

Exhibit B - Materials Reviewed and Considered (Amended and Supplemental)

- Third Amended Consumer Economic Loss Class Action Complaint, dated Nov. 1, 2021
- Expert Report of L. Plunkett, Ph.D., dated Oct. 31, 2022, and all documents cited therein
- Deposition of L. Plunkett, Ph.D., dated Jan. 12, 2023, and exhibits
- Expert Report of R. Najafi, Ph.D., dated Nov. 4, 2021
- Expert Report of R. Najafi, Ph.D., dated Oct. 31, 2022, and all documents cited therein
- Deposition of R. Najafi, Ph.D., dated Jan. 18 & 24, 2023, and exhibits
- Expert Report of S. Bain, dated Oct. 31, 2022, and all documents cited therein
- Deposition of S. Bain, dated Jan. 31, 2023, and exhibits
- Expert Report of S. Hecht, Ph.D., dated Oct. 31, 2022, and all documents cited therein
- Expert Report of S. Hecht, Ph.D., dated July 6, 2021
- Deposition of S. Hecht, dated Jan. 13, 2023, and exhibits
- P. Dong Deposition Transcript with Exhibits, dated Mar. 29, 2021
- P. Dong Deposition Transcript with Exhibits, dated Mar. 30, 2021
- P. Dong Deposition Transcript with Exhibits, dated Mar. 31, 2021
- P. Dong Deposition Transcript with Exhibits, dated Apr. 1, 2021
- P. Dong Deposition Transcript with Exhibits, dated Apr. 2, 2021
- J. Du Deposition Transcript with Exhibits, dated May 27, 2021
- J. Du Deposition Transcript with Exhibits, dated May 28, 2021
- E. Gu Deposition Transcript with Exhibits, dated Apr 5, 2021
- E. Gu Deposition Transcript with Exhibits, dated Apr. 6, 2021
- J. Ge Deposition Transcript with Exhibits, dated May 26, 2022
- J. Ge Deposition Transcript with Exhibits, dated May 27, 2022
- J. Ge Deposition Transcript with Exhibits, dated Apr. 27, 2021
- J. Ge Deposition Transcript with Exhibits, dated Apr. 28, 2021
- J. Ge Deposition Transcript with Exhibits, dated Apr. 29, 2021
- J. Ge Deposition Transcript with Exhibits, dated Apr. 30, 2021
- R. Gergis Deposition Transcript with Exhibits, dated Feb. 2, 2021
- M. Li Deposition Transcript with Exhibits, dated Apr. 20, 2021
- M. Li Deposition Transcript with Exhibits, dated Apr. 21, 2021
- M. Li Deposition Transcript with Exhibits, dated Apr. 22, 2021
- Q. Li Deposition Transcript with Exhibits, dated Apr. 13, 2021
- Q. Li Deposition Transcript with Exhibits, dated Apr. 14, 2021
- Q. Li Deposition Transcript with Exhibits, dated Apr. 15, 2021
- Q. Li Deposition Transcript with Exhibits, dated Apr. 16, 2021
- H. Wang Deposition Transcript with Exhibits, dated Mar. 10, 2021
- H. Wang Deposition Transcript with Exhibits, dated Mar. 11, 2021
- M. Zhang Deposition Transcript with Exhibits, dated Mar. 22, 2021
- M. Zhang Deposition Transcript with Exhibits, dated Mar. 23, 2021
- M. Zhang Deposition Transcript with Exhibits, dated Mar. 24, 2021
- M. Zhang Deposition Transcript with Exhibits, dated Mar. 25, 2021
- M. Zhang Deposition Transcript with Exhibits, dated Mar. 26, 2021
- 21 C.F.R. § 10.115
- 21 C.F.R. § 210.1
- 21 C.F.R. § 210.3
- 21 C.F.R. § 211.100
- 21 C.F.R. § 211.186

- 21 C.F.R. § 211.188
- 21 C.F.R. § 314.3
- 21 C.F.R. § 314.420
- 21 C.F.R. § 314.50
- 21 C.F.R. § 314.70
- 21 C.F.R. § 314.94
- 21 C.F.R. § 314.97
- 21 C.F.R. § 320.1
- 21 C.F.R. §§ 7.1-7.59
- 21 C.F.R. §§ 7.3
- 21 U.S.C. § 351
- Chemical & Engineering News, NDMA, a contaminant found in multiple drugs, has industry seeking sources and solutions (available at: <https://cen.acs.org/articles/98/i15/NDMA-contaminant-found-multiple-drugs.html>)
- European Medicines Agency, Guideline on the Limits of Genotoxic Impurities (valid from Jan. 1, 2007 to Jan. 31, 2018) (available at: https://www.ema.europa.eu/en/documents/scientific-guideline/guideline-limits-genotoxic-impurities_en.pdf)
- European Medicines Agency, Questions and answers on the 'Guideline on the limits of genotoxic impurities' (valid from Sep. 24, 2010 to Jan. 31, 2018) (available at: https://www.ema.europa.eu/en/documents/scientific-guideline/questions-answers-guideline-limits-genotoxic-impurities_en.pdf)
- F. Sörgel et al., The contamination of valsartan and other sartans, part 1: New findings, 172 J Pharm Biomed Anal. 395, 396 (2019), doi: 10.1016/j.jpba.2019.05.022 (available at: <https://www.sciencedirect.com/science/article/abs/pii/S0731708519302183?via%3Dihub>)
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- FDA Q3A, Attachment 3 (available at: <https://www.fda.gov/media/71733/download>)
- FDA Q3A, Guidance for Industry Q3A Impurities in New Drug Substances (available at: <https://www.fda.gov/media/71727/download>)
- FDA Q7 Good Manufacturing Practice Guidance for Active Pharmaceutical Ingredients: Guidance for Industry (available at: <https://www.fda.gov/files/drugs/published/Q7-Good-Manufacturing-Practice-Guidance-for-Active-Pharmaceutical-Ingredients-Guidance-for-Industry.pdf>)
- FDA Q8(R2), Guidance for Industry Q8(R2) Pharmaceutical Development (available at: <https://www.fda.gov/media/71535/download>)
- FDA Q9, Guidance for Industry Q9 Quality Risk Management (available at: <https://www.fda.gov/media/71543/download>)
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- FDA, Completeness Assessments for Type II API DMFs Under GDUFA Guidance for Industry (Oct. 2017) (available at: <https://www.fda.gov/media/84217/download>)

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- FDA, Compliance Program Guidance Manual: Program 7356.002 (available at: <https://www.fda.gov/media/75167/download>)
- FDA, Compliance Program Guidance Manual: Program 7356.002F (available at: <https://www.fda.gov/media/75201/download>)
- FDA, Contract Manufacturing Arrangements for Drugs: Quality Agreements Guidance for Industry
- FDA, Current Good Manufacturing Practice (CGMP) Regulations (current as of 11/16/2022) (available at: <https://www.fda.gov/drugs/pharmaceutical-quality-resources/current-good-manufacturing-practice-cgmp-regulations>)
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- FDA, Drugs@FDA: FDA-Approved Drugs, NDA 021283 (available at: <https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=021283>)
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- FDA, Regulatory Procedures Manual § 4-1-8 (June 2022) (available at: <https://www.fda.gov/media/71878/download>)
- FDA, Types of Drug Master Files (DMFs) (last updated 01/27/2021) (available at: <https://www.fda.gov/drugs/drug-master-files-dmfs/types-drug-master-files-dmfs>)
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- FDA, Zhejiang Huahai Pharmaceutical Co., Ltd. - FEI No: 3003885745 (available at: <https://datadashboard.fda.gov/ora/firmprofile.htm?FEIs=3003885745>)
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- ICH Q11 (available at: <https://www.fda.gov/files/drugs/published/Q11-Development-and-Manufacture-of-Drug-Substances.pdf>)
- ICH Q3A (available at: <https://database.ich.org/sites/default/files/Q3A%28R2%29%20Guideline.pdf>)
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- ICH Q7 (available at: <https://database.ich.org/sites/default/files/Q7%20Guideline.pdf>)
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- ICH Q9 (available at: <https://database.ich.org/sites/default/files/Q9%20Guideline.pdf>)
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- Expert Report of David L. Chesney, MSJ, dated Jan. 12, 2022
- D. Chesney Deposition Transcript with Exhibits, dated Mar. 21, 2022
- Expert Report of F. Xue, Ph.D, dated Dec. 22, 2022
- Deposition of F. Xue, Ph.D, dated Feb. 3, 2023

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PRINSTON00069246	PRINSTON00276496	ZHP01459834	
PRINSTON00069275	PRINSTON00279740	ZHP01459881	
PRINSTON00069294	PRINSTON00280178		